

## **REMARKS**

Applicants have carefully reviewed the Office Action mailed on July 20, 2010 and the Advisory Action mailed October 5, 2010. Claims 20, 24, 28, and 29 have been amended. Support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added. Applicants respectfully traverse all objections, rejections and assertions made by the Examiner. Claims 20-29 are pending.

### **Claim Rejections under 35 U.S.C. § 103**

Claims 20-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Puno (US 5,360,431) in view of Mathews (US 6,033,406) and Foley (US 5,792,044) and Davison (US 2001/0011170). This rejection is respectfully traversed. Independent claim 20, as amended, recites:

20. (currently amended) A method of treating the spine of a patient, comprising:

inserting an access device through an incision in the skin of the patient generally posteriorly until a distal portion of the access device is located adjacent the spine of the patient, said access device being inserted in a first configuration having a first cross-sectional area at the distal portion thereof;

actuating said access device to a second configuration having an enlarged cross-sectional area at said distal portion thereof that spans at least a portion of a first vertebra, at least a portion of a second vertebra, and at least a portion of a third vertebra;

placing a fusion device through the access device and in at least one of a first interbody space between the first and second vertebrae and a second interbody space between the second and third vertebrae;

performing a two level fixation procedure spanning the first and second interbody spaces through the access device by inserting at least one fastener into each of the first, second, and third vertebrae and attaching an elongated member to the fasteners, wherein the fastener includes a screw and a U-shaped housing adapted to receive a joint region of the screw and the elongated member, wherein the housing and joint region are configured to allow movement of the housing relative to the screw to achieve a desired orientation of the elongated member with respect to the housing;

advancing a decompression tool through the access device; and  
removing a portion of bone from one of the first vertebrae, the second vertebrae, and the third vertebrae through the access device;

wherein the steps of placing the fusion device in an interbody space, inserting fasteners into first, second, and third vertebrae, attaching an elongated member to the fasteners, advancing a decompression tool, and removing a portion

of bone from a vertebrae are all performed through the same access device with the access device inserted in the same incision.

None of Puno, Mathews, Foley, or Davison, either alone or in combination, appear to teach or suggest the specifically recited method steps. The rejection is thus an error. Puno appears to teach an open surgical procedure for inserting 6 pedicle screws, 2 rods, and one or more cross-linking members, as shown in FIGS. 14-20. In particular, Puno teaches an open surgical procedure for performing a two-level spinal fixation:

Initially, the area of implantation is surgically approached. A longitudinal posterior midline incision is made over the spine. The incision is carried through the subcutaneous tissue and the fascia to the tips of the spinous processes. Subperiosteal dissection is performed over the laminae and transverse processes. The facet capsule and articular cartilage are removed in preparation for fusion.

See column 6, lines 50-57. The Examiner acknowledges that Puno fails to teach inserting an access device and performing their surgical procedures through an access device. Davison is asserted as teaching a method involving inserting an access device, actuating the access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of the multiple vertebrae, and performing various surgical procedures, such as decompression and fixation procedures, through the access device. The Examiner has not provided an indication of where in Davison a teaching is found of the enlarged cross-sectional area at said distal portion thereof that spans at least a portion of a first vertebra, at least a portion of a second vertebra, and at least a portion of a third vertebra. While Davison teaches the “expandable second tubular portion 180 of the cannula 150 provides a significantly larger working area for the surgeon inside the body” which results in “the simultaneous use of a number of endoscopic surgical instruments, including but not limited to steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and video cameras” (paragraph 52), there is no teaching or suggestion that the expanded distal portion of Davison would be configured to span at least a portion of each of a first vertebra, a second vertebra, and a third vertebra. The Examiner asserts that because Davison states that the disclosed invention is not meant to be limited to use with the outlined instruments or any specific procedures, that it would have been obvious to perform the multi-level fixation procedure of Puno through the access device of Davison because Davison teaches their device as being large enough to allow passage of multiple instruments while reducing the amount of trauma the patient experiences. Applicants

respectfully disagree. The mere fact that Davison teaches their device as allowing the simultaneous passage of multiple instruments cannot be seen as a teaching that the device is configured to span at least a portion of a first vertebra, at least a portion of a second vertebra, and at least a portion of a third vertebra.

Further, Davison appears to teach a device for performing endoscopic procedures, stating the “present invention is applicable to a variety of surgical procedures in which endoscopic surgical techniques are used.” See paragraph [0017]. Davison also teaches, “[s]urgical instruments are inserted into the body during endoscopic surgery through the passage 16.” See paragraph [0018]. Davison further teaches:

The expandable second tubular portion 40 of the cannula 10 provides a significantly larger working area for the surgeon inside the body 130 within the confines of the cannula. As a result, the simultaneous use of a number of endoscopic surgical instruments, including but not limited to steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and video cameras, is made possible by the expandable cannula 10.

See paragraph [0035]. Davison thus appears to teach their device as being applicable to endoscopic surgical techniques. Davison does not, however, appear to teach anything regarding performing a multi-level fixation technique involving the insertion of multiple screws and rods, as taught by Puno, using their device. Applicants submit that the mere fact that Davison states their device is not meant to be limited to use with the outlined instruments cannot be seen as any motivation or guidance for attempting to perform the multi-level fixation procedure of Puno through the device of Davison.

Additionally, one of ordinary skill in the art would understand that the type of endoscopic surgical instruments described by Davison, such as steerable instruments and dissectors, are quite different in size and shape compared to the multiple screw and rod assembly inserted in the method of Puno. This is evidenced by the fact that Foley teaches performing endoscopic procedures involving multiple instruments, through a fixed diameter cannula, while Puno appear to teach their multi-level fixation procedure as being performed using an open surgical procedure. One of ordinary skill in the art would have no motivation or expectation of success in attempting to perform the procedure shown in FIGS. 17-20 of Puno through the device of Davison, which appears to teach performing endoscopic procedures. The only such motivation is found in Applicant’s disclosure, which is improper.

MPEP 2143.01 III states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless **\*\*>**the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007)

Emphasis original. Applicants submit that attempting to perform the complex, open surgical procedure of Puno through the device of Davison would not have given predictable results. As discussed above, Davison appears to teach, “[s]urgical instruments are inserted into the body during endoscopic surgery through the passage 156.” See paragraph [0036]. In view of the teachings of Davison, Applicants submit that the only reason or motivation for one of ordinary skill in the art to attempt to perform the procedures of Puno through the device of Davison is found in Applicants’ specification, which is an error. The Examiner appears to be relying on Applicants’ disclosure and hindsight rather than the actual teachings of the references, in order to make a determination of obviousness. Applicants submit there is nothing in Puno to suggest or lead one of ordinary skill in the art to attempt to perform their open procedure of inserting multiple screws, rods, and cross-linking members through a device described as allowing passage of endoscopic instruments. Neither Matthews nor Foley appear to provide any rational reason or motivation for modifying Puno as asserted by the Examiner.

In the Response to Arguments section of the final Office Action on page 5, the Examiner states that, “[u]nder the TSM Test a claimed invention is obvious when there is a teaching, suggestion, or motivation to combine prior art teachings and has no requirement for establishing predictable results.” The Examiner appears to be acknowledging that there is no predictability in combining Puno, Davison, Matthews, and Foley, and is thus not relying on the KSR arguments. The Examiner appears to be relying solely on the TSM test, rather than the tests set forth in the KSR decision. The Examiner further states, “examiner has provided the differences between the prior art references and the claimed invention and has provided a teaching reference with a motivation for one having ordinary skill in the art to combine the prior art teachings as required by the TSM Test (MPEP 2141).” Applicants respectfully disagree. As discussed above, Puno appears to teach an open surgical technique for inserting 6 pedicle screws, 2 rods, and one or more cross-linking members, as shown in FIGS. 14-20. Davison, however, appears to teach that, “the simultaneous use of a number of endoscopic surgical instruments, including but not limited to steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and video

cameras, is made possible by the expandable cannula 10.” See paragraph [0035]. Davison thus appears to provide motivation, if at all, for one of ordinary skill in the art to perform an endoscopic procedure involving multiple instruments, through their device instead of an endoscope. Puno does not appear to teach an endoscopic procedure, and the Examiner has not asserted that Puno is related to endoscopic procedures. The asserted teaching, suggestion, or motivation provided by Davison does not appear to be related to the type of procedure taught by Puno. One of ordinary skill in the art, upon reading Puno and Davison, would not have seen any teaching, suggestion, or motivation for attempting to use the device of Davison, taught as an advantage for endoscopic procedures, in the open surgical procedure of Puno. Taking into account only knowledge that was within the level of ordinary skill at the time the claimed invention was made, and not including Applicants’ disclosure, there is no teaching, suggestion or motivation for the skilled artisan to attempt the open surgical procedure of Puno using the device of Davison. Applicants submit the missing part of the Examiner’s argument using TSM is some teaching, suggestion, or motivation in a reference that the open surgical procedure of Puno could be performed endoscopically. The cited references fail to provide such a teaching, suggestion, or motivation. The rejection is thus an error. Reconsideration and withdrawal of the rejection are respectfully requested.

**Conclusion**

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 767-4574.


Respectfully submitted,

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By their Attorney,

Date: \_\_\_\_\_

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